

REMARKS

Reconsideration of this application is respectfully requested.

Claims 1-88 have been canceled. Claims 89-151 were added in the Amendment filed March 1, 2005, but have not yet been entered. New claims 152-171 are derived from claims 61-64, 87, and 88, and are fully supported by the specification.

Double Patenting Rejections

Claims 61-64, 87, and 88 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,525,243; claims 1-10 and 13-21 of U.S. Patent No. 6,147,276; and claims 11-18 of U.S. Patent No. 6,252,133 B1. Solely to expedite allowance of the pending claims, and not in acquiescence to this rejection, applicants will submit Terminal Disclaimers in compliance with 37 C.F.R. § 1.321(c) when the claims are otherwise indicated to be allowable.

Rejections under 35 U.S.C. § 101

Claims 61-64, 87, and 88 were rejected under 35 U.S.C. § 101 as allegedly being directed to non-statutory subject matter. The Office contends that the pending claims do not sufficiently distinguish over naturally occurring mammals and "lack evidence of the hand-of-man." (Paper No. 20 at 7.)

Applicants traverse the rejection. New claims 152-171 recite a live-born clone of a pre-existing, non-embryonic, donor mammal. A clone of a pre-existing, non-embryonic, donor mammal is never found in nature because the clone is produced asexually. Nature does not make copies of such mammals. The Office does not contest this point. Consequently, the hand-of-man is required for applicants' clone to

exist. Although applicants' clone is a copy, or replica, of a previously known mammal, it is not the same mammal because, among other things, it occupies a different space and time than the previously known mammal. Accordingly, applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 87 and 88 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Office contends that the specification does not support the term "parental."

Applicants traverse the rejection. Although not using the word "parental" specifically, the specification refers to the "parental" animal in cloning as the "donor." (See, e.g., at page 1, lines 9-12: "The reconstruction of mammalian embryos by the transfer of a donor nucleus to an enucleated oocyte or one cell zygote allows the production of genetically identical individuals. This has clear advantages for both research (i.e. as biological controls) and also in commercial applications (i.e. multiplication of genetically valuable livestock, uniformity of meat products, animal management).") It is clear that, in the "multiplication of genetically valuable livestock," the donor animal for nuclear transfer is the "parental" animal. Thus, the term "parental" has inherent support in the specification. In addition, applicants' new claims 152-171 do not recite the term "parental." Thus, these claims obviate the rejection.

Claims 61-64, 87, and 88 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for cloned primates. Applicants traverse the rejection.

Any conclusion regarding the cloning of primates must take into account the low efficiency of the cloning process. As noted in Pennisi and Vogel, "[f]irst and foremost is the problem of efficiency" and "Dolly was the product of 434 attempts at nuclear

transfer, all but one of which went bad. With respect to primates, Pennisi and Vogel state that there have been “300 attempts and no pregnancies.” Based on these numbers, the known inefficiency of the cloning process can account for the lack of reported success in primates. Accordingly, the Office’s conclusion that cloning in primates was unpredictable is in error.

In addition, applicants’ new claims 152-171 recite that the mammal is selected from cattle, sheep, pigs, goats, mice, rabbits, horses, and rats. Thus, these claims obviate the rejection.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 87 and 88 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite in reciting the term “parental.”

Applicants traverse the rejection. Applicants submit that that the skilled artisan would understand the meaning of claims 87 and 88 as referring to the “donor” as the parent. Moreover, as discussed above, new claims 152-171 do not recite these terms, and thus the rejection is moot.

Rejections under 35 U.S.C. § 102(b) and/or 103(a)

Claims 61-64, 87, and 88 were rejected under 35 U.S.C. § 102(b) and/or 103(a) over several publications that teach the production of embryos and mammals. (Massey, 1991; Campbell and Marshall, 1975; and Sims et al., 1991). It is the Office’s position that the mammals of the prior art anticipate or make obvious applicants’ claimed clones because there is no patentable distinction between the prior art mammals and applicants’ claimed clones.

Applicants traverse the rejection. The prior art mammals cited by the Office are missing a limitation of applicants’ claims, namely, one of the mammals is not a clone of

a pre-existing, non-embryonic, donor mammal. Therefore, the cited prior art cannot anticipate applicants' claims, and applicants respectfully request withdrawal of the rejection.

Moreover, the cited prior art cannot make obvious applicants' claims. Nowhere does the cited prior art teach or suggest that one of the animals is a clone of a pre-existing, non-embryonic, donor mammal. Thus, the cited prior art cannot make applicants' claims obvious, and applicants respectfully request withdrawal of the rejection.

Furthermore, a distinguishing feature of applicants' claimed mammals is that applicants' clone creates a situation that never existed prior to applicants' invention. This situation involves the existence of a non-embryonic, donor mammal prior to the existence of a clone of that mammal. Thus, one is able to physically examine applicants' donor mammal prior to the generation of a clone of that mammal. The benefits of this situation are readily apparent and cannot be considered obvious from the animals found in the prior art.

Prior to applicants' invention, no mammal existed that had the same set of chromosomes as (i.e., was a clone of) its parent. This is an unexpected property of applicants' clone. This property of applicants' clone allows one to distinguish between it and sexually produced mammals. (February 26, 2003, Declaration of David Wells at ¶¶5-23.)

Conclusion

Applicants respectfully submit that this application is now in condition for allowance. If the Examiner believes that issues remain to be addressed before a Notice of Allowance, applicants respectfully request that the Examiner contact the undersigned to discuss any outstanding issues.

If there is any fee due in connection with the filing of this Amendment, please charge the fee to Deposit Account No. 06-0916.

Respectfully submitted,

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